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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/045,904 | 11/07/2001 | David S. Strayer | STR01-NP007 | 1373 |

24358 7590 03/26/2003

THOMAS JEFFERSON UNIVERSITY
INTELLECTUAL PROPERTY DIVISION
1020 WALNUT STREET
SUITE 620
PHILADELPHIA, PA 19107

EXAMINER

CHOI, FRANK I

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1616

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,904

Applicant(s)

STRAYER, DAVID S.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-8,12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the acknowledged prior art in view of Chander et al. (1990).

Applicant acknowledges that pulmonary surfactant is secreted by type II pneumocytes and acts to reduce surface tension so that less effort is needed to re-inflate the lungs (Pgs. 1, 2). It is acknowledged that calcium ionophores, such as ionomycin, cause surfactant secretion by release of calcium from ER stores directly and carry calcium from outside the cell into the cytosol and that thapsigargin stimulates surfactant secretion by acting directly on calcium stores to increase concentration of calcium in cytosol stores (Pgs. 2, 3). It is further acknowledged that diseases of surfactant deficiency are characterized by respiratory distress (Pg. 5).

Chander teaches that positive modulators of surfactant secretion in type II cells include calcium ionophores in the presence or external calcium and verapamil, a calcium channel blocker, in concentrations inhibiting calcium uptake, increased surfactant secretion (Pg. L246).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose methods of treating or inhibiting respiratory distress by administering a therapeutically effective amount of an agent that activates surfactant secretion in said mammal. However, the prior art amply suggests the same as the prior art teaches that certain compounds

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which effect the concentration of calcium in type II pneumocytes are known to increase the secretion of pulmonary surfactant and that pulmonary surfactant deficiency is characterized by respiratory distress. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to administer the agents above with the expectation that the increase in pulmonary surfactant secretion would be effective in treating or inhibiting respiratory distress.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the acknowledged prior art in view of Strayer et al. (1999).

Applicant acknowledges that pulmonary surfactant is secreted by type II pneumocytes and acts to reduce surface tension so that less effort is needed to re-inflate the lungs (Pgs. 1, 2). It is acknowledged that calcium ionophores, such as ionomycin, cause surfactant secretion by release of calcium from ER stores directly and carry calcium from outside the cell into the cytosol and that thapsigargin stimulates surfactant secretion by acting directly on calcium stores to increase concentration of calcium in cytosol stores (Pgs. 2, 3). It is further acknowledged that diseases of surfactant deficiency are characterized by respiratory distress (Pg. 5).

Strayer et al. teach that BAPTA-AM, a calcium channel chelators, stimulates surfactant secretion in type II pneumocytes and BAPTA-AM at concentration greater than 10 microMolar up to about 100 microMolar resulted in an increase in surfactant secretions without significantly effecting the viability of the pneumocytes (pg. 42).

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The difference between the prior art and the claimed invention is that the prior art does not expressly disclose methods of treating or inhibiting respiratory distress by administering a therapeutically effective amount of an agent that activates surfactant secretion in said mammal. However, the prior art amply suggests the same as the prior art teaches that certain compounds which effect the concentration of calcium in type II pneumocytes are known to increase the secretion of pulmonary surfactant and that pulmonary surfactant deficiency is characterized by respiratory distress. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to administer the agents above with the expectation that the increase in pulmonary surfactant secretion would be effective in treating or inhibiting respiratory distress.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

March 23, 2003


JOHN PAK
PRIMARY EXAMINER
GROUP 1600

